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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/582,817      | 11/08/2000  | Jose Remacle         | VANM160.001A        | 2892             |

20995 7590 03/28/2006

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/582,817 | <b>Applicant(s)</b><br>REMACLE, JOSE |  |
|                              | <b>Examiner</b><br>Bradley L. Sisson | <b>Art Unit</b><br>1634              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 30-34, 40, 41, 45, 49 and 51-64 is/are pending in the application.
- 4a) Of the above claim(s) 32, 33, 49 and 51-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30, 31, 34, 40, 41, 45 and 64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Specification***

1. The disclosure is objected to because of the following informalities: At page 7, lines 17-20 and 28-29, the term “lecture” is used in a manner inconsistent with common American usage. Similar issues of clarity exist at page 17, line 2 where the phrase “safety constraint legislations” is used; and at page 20, line 3, where the term “convoyed” is used.

**New Matter.**

2. The amendment to claims received 17 June 2005 inserted language into claim 30 stipulating that the “microchannels are not grooves.” Page 7 of the response pointed to three parts of the original disclosure as providing support for this limitation, namely” page 7, lines 28-31; page 18, lines 27-30; and page 20, lines 1-3. A review of these passages fails to find support for the limitation added to the claims. For convenience, the cited passages are reproduced below. Page 7, lines 28-31.

The disc can incorporate grooves to conduct the lecture by a laser beam. In said grooves are  
30 incorporated “registered” data that can be thereafter analyzed and advantageously transcribed into digital data.

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Page 18, lines 27-30.

compact-disc according to the invention also contains data which allows the disc to be read in an laser-based CD reader (information usually stored as a series of pits 30 located in the disc grooves and which are necessary to localize the non-cleavable capture molecule on the surface of the disc). This can be obtained through the presence of

Page 20, lines 1-3.

arising from the rotation of the disc. The liquid is projected through inlet pits to enter the disc and then conveyed through microchannels until binding chambers (see

3. A review of these passages finds only one instance where the term “microchannels” is used, and then there is no indication as to there being a limited definition of the term.

Accordingly, no support has been located for the negative limitation that the “microchannels are not grooves.”

Appropriate correction is required.

4. The use of the trademark TWEEN has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 31, 34, 40, 41, 45, and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when

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determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

For convenience, claim 30, the sole independent claim under consideration, is reproduced below.

30. **(Currently amended)** A method for a detection and/or quantification of a target molecule present in a sample, comprising the steps of:

- allowing binding between said target molecule and a capture molecule fixed upon a side of the surface of a solid support, said solid support consisting of a compact disc (CD) or digital video disc (DVD) comprising registered data that can be read by a CD reading device,

- wherein said binding occurs in areas separated from areas comprising registered data,

- wherein said CD or DVD is not rotating on its axis and does not comprise microchannels,

- wherein said microchannels are not grooves;

- wherein capture molecules are located on areas of said disc that do not comprise ~~any grooves or~~ registered data, and

- wherein the target and capture molecules are nucleic acid molecules or proteins;

- removing unbound target molecules;

- treating said CD or DVD in order to obtain a detectable signal resulting from the binding of the target molecule and said capture molecule,

- wherein said binding results in a precipitate on said CD or DVD,

- wherein said CD or DVD is not rotating on its axis;

- detecting said signal, wherein said signal is not obtained through cleavage of the capture molecule, and

reading the registered data by a first reading device and reading by a second reading device the signal resulting from the binding between said target molecule and said capture molecule, wherein said registered data is binary data which comprises characteristics and position of capture molecules fixed upon specific areas of said CD or DVD or interpretation of the signal resulting from the binding between the target and the capture molecules, wherein said readings being done when the disc is rotating on its axis in an apparatus comprising the two different reading devices.

6. In accordance with the method of claim 30, one is to conduct the assay where the capture molecules are fixed on one side of the disc, which can be a CD or DVD. Such an initial step fairly encompasses grooves as well as pits found in the grooves. Page 18 of the specification, however, states that it is “necessary” to localize the non-cleavable capture molecule on the surface of the disc. Accordingly, the specification has not been found to teach, much less enable the detection of any target molecule where the binding does not take place in the pits found in the grooves.

7. Page 10 of the specification states that in reading the data stored in the disc surface, “[t]he depth of the pit is engineered to be  $\frac{1}{4}$  of the wavelength of the laser light.” As seen above, the capture, and target molecules are bound to one another, and to the side of the disc in just such a place. Upon review of the examples, it is noted that Example 1, page 28, states, “a picture was taken of this CD.” Clearly, the aspect of taking a picture of this CD does not teach the method steps, reaction conditions, or claimed method steps of the now claimed invention.

8. Example 2 teaches the detection of DNA on a CD with “maser” [*sic*, laser] beam detection.” As seen therein, the CD was:

- a. first coated with a capture probe,
- b. a biotinylated DNA hybridized to said capture probe

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- c. streptavidin-gold reacted with the hybridization complex
- d. Silver Enhancement was conducted “in order to have silver precipitate where positive hybridization occurred,” and
- e. “This CD was recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the information written on the CD and to read the interference due to silver precipitate.”

9. The method of claim 30 does not recite the limitations of steps b) through e). Further, the specification, which teaches explicitly that the pits are engineered to have a depth of  $\frac{1}{4}$  wavelength of the laser, is silent as to how these same pits are to be read when they comprise multiple layers of material, as well as overlays of gold. And as seen in Example 4, the assay may well comprise precipitate that is 1  $\mu\text{m}$  in diameter, over which gold may be plated.

10. While the claims and Example 2 teach that the disc may contain information as to how the disc reader may interpret the information, the specification is essentially silent as to how artifacts, variances in particle/precipitate size, or noble metal over layering is to be taken into account.

11. As a result of various amendments to claim 30, said claim now recites that the disc is read by a device that comprises “the two different reading devices.” Clearly, the aspect of having “an apparatus comprising the two different reading devices” is critical to enabling the claimed invention. The specification, however, is essentially silent as to how such a device is to be made and used. Of the five examples provided, none of the examples actually teach using a device in accordance with the now claimed method. Example 2 is the most relevant to the claimed invention, and then it does not state that the disc was actually read, much less that it provided any



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useful information. And it certainly does not teach that the disc was read by a device that comprised “the two different reading devices.” In Example 4, a disc was apparently read, but then, the reader used was only a single reader, not the required combined reading device. While the specification teaches that “[t]he presence of pits was found by reflection of the laser beam,” such teachings do not address how one would be able to differentiate between actual test signals and false positives. And like Example 2, the specification does not teach using a device that comprises both reading devices, much less reading binary data and test results.

12. In view of the breadth of scope claimed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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14. Claims 30, 31, 34, 40, 41, 45, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/035822. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '822 application fairly teach or suggest the method of detection and/or quantification of a target molecule wherein a binding assay takes place on the surface of a disc, and which comprises binary data.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 30-34, 40, 41, 45, 49, and 51-64 of this application conflict with claims 1-45, 48, and 50-88 of Application No. 10/035,822. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

### ***Conclusion***

16. Rejections that appeared in the non-final Office action of 05 July 2005, and not repeated hereinabove, have been withdrawn.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
18 March 2006